

Notice of Allowability

Application No.

10/631,887

Examiner

Robert Shiao

Applicant(s)

CHOLODY ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to responses filed on 01/24/2006.
2. ☒ The allowed claim(s) is/are 1-20, 40-41, now are 1-22.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date ____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date ____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____. |

DETAILED ACTION

1. Amendment of claims 1, 8-14, 16, and 40 in the amendment filed on January 24, 2006, is acknowledged. Claims 1-41 are pending in the application.

Responses to Amendment

2. Since the limitation of the variable R_5 of formula (I) or (II) has been incorporated into claim 1, therefore, rejection of claims 1-19 and 40-41 under 35 U.S.C. 112, second paragraph, has been overcome in the amendment filed on January 24, 2006.

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Authorization for this examiner's amendment was given in a telephone interview with Alan J. Grant on March 03, 2006. The application has been amended as follows:

In claim 1, lines 8-9, after "unsubstituted arylalkyl," delete "substituted and unsubstituted heteroarylalkyl,"

In claim 1, line 15, after "unsubstituted arylalkyl," delete "substituted and unsubstituted heteroarylalkyl,"

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In claim 1, page 3, lines 2-3, after "unsubstituted arylalkyl," delete "substituted and unsubstituted heteroarylalkyl,"

In claim 1, page 3, lines 9-10, after "pyridine," delete "substituted and unsubstituted heteroarylalkyl,"

In claim 1, page 3, line 16, after "pyridine," delete "substituted and unsubstituted heteroarylalkyl,"

In claim 4, page 4, lines 1-2, after "unsubstituted arylalkyl," delete "substituted and unsubstituted heteroarylalkyl,"

In claim 20, lines 1-2, after "A method for", delete "preventing or treating a disease associated with a change in levels of expression of members of a gene set", and insert

--treating colon cancer--

In claim 40, page 11, lines 11-12, after "3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 2-[(1-benzyl-piperidin-3-yl)-amide] 4-hydroxyamide,"
insert

--3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 4-hydroxyamide 2-piperidin-1-ylamide,--

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In claim 40, page 11, lines 23-24, **delete** "3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 2-[(1-benzyl-pyrrolidin-3-yl)-amide] 4-hydroxyamide, "

In claim 40, page 13, lines 27-28, **delete** "3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 4-hydroxyamide 2-[(1-methyl-1H-pyrrol-2-ylmethyl)-amide], "

In claim 40, page 14, lines 1-4, **delete** "3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 4-hydroxyamide 2-[(2-phenyl-1H-thiazol-4-ylmethyl)-amide],

3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 2{[2(5-dimethylaminomethyl-furan-2-ylmethylsulfanyl)-ethyl] amide} 4-hydroxyamide, "

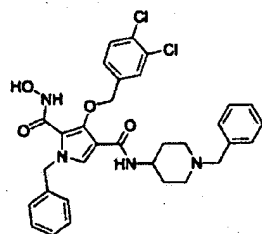
In claim 40, page 14, lines 9-18, **delete** "3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 4-hydroxyamide 2-[[2-trifluoromethyl-quinolin-4-ylsulfanyl)-ethyl]amide},

3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 2-(3-pyrrol-1-yl-benzylamide),

3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 4-hydroxyamide 2-(4-[1,2,3]thiadiazol-4-yl-benzylamide),

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3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 4-hydroxyamide 2-(4-thiophen-3-yl-benzylamide),
 3-(3,4-Dichloro-benzyloxy)-1-methyl-1H-pyrrole-2,4-dicarboxylic acid 2-[(2,3-dihydrobenzol[1,4]dioxin-6-ylmethyl)-amide]4-hydroxyamide, “



In claim 41, after “ ”, insert

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Delete claims **21-39**

Reasons for Allowance

4. The following is an examiner's statement of reasons for allowance:

Claims 1-19 and 40-41 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claim 20, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claim 20 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on January 19, 2005, is hereby withdrawn, in part.

Claims 1-20 and 40-41 are neither anticipated nor rendered obvious over the art of record, and therefore are allowable. This invention relates to derivatives of 3-hydroxy-pyrrole-2,4-dicarboxylic acid and uses thereof. The closest reference is Hale et al. US 6,750,239, which discloses pyrazole-derived kinase inhibitors and use thereof. The difference between Hale et al. and instant claims is that the instant compounds of formula (I) or (II) have not been found. A suggestion for modification of above record to obtain the instant claimed compounds/compositions and methods of use, has not been found. Claims 1-20 and 40-41 are allowed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

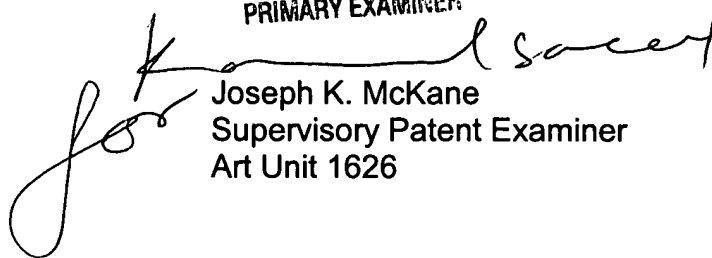
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph

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K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KAMALA A. SAEED, PH.D.
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Joseph K. McKane', is written over the printed name and title.

Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626

R.S.

Robert Shiao, Ph.D.
Patent Examiner
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March 06, 2006